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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,014	12/04/2001	Chen Xing Su	10209.276	6898

21999 7590 12/14/2005

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,014	SU ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and request for continued examination, all received on 25 November 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to methods of treating pain where the total daily dosage of *Morinda citrifolia* juice is less than 0.1 mL per kg of body weight of a patient. There is no support in the instant specification for such a claim limitation. The instant specification contains only a very broad disclosure on Page 15 that suggests that increasing amount of *Morinda citrifolia* juice may not necessarily be more beneficial. There is no specific disclosure that provides guidance for selecting the particular upper limit of 0.1 mL per kg of body weight of a patient.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-10, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over Gidlund is maintained.

Response to Arguments

The applicant's arguments, received on 25 November 2005, have been considered, but are not found to be persuasive.

The applicant argues that the Gidlund reference teaches the administration of an extract, which the applicant defines as certain ingredients that are isolated from the juice of a fruit. However, the prior art does not specify a particular component that is allegedly isolated from the juice of *Morinda citrifolia* fruit. The examiner notes that the juice, as recited in the instant claims, is processed by techniques of pasteurization and filtration. In the view of the examiner, there is no patentable difference between the juice recited by the applicant as processed, and the juice as disclosed in the prior art, "treated in the way conventional to the art". Furthermore, the applicant's own disclosure lacks any specific definition of juice. How much or how little processing can be applied to a liquid taken from a fruit and still be called "juice" has not been clearly defined by the applicant. Even so, the applicant has not shown how the presence of certain components found in juice that would not be allegedly found in a fruit extract imparts the selective COX-2 inhibition as instantly claimed by the applicant.

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The examiner considers the property of selective cyclooxygenase-2 inhibition to be implicit and inherent to the disclosure of the prior art. As the art has already shown guidance that the invention of the Gidlund reference is useful for treating various conditions of pain, such as menstrual cramps, arthritis, sprains, and injuries, the examiner considers such a disclosure to be further guidance and evidence towards that rationale. The applicant is reminded that a composition known in the prior art does not become patentable upon the discovery of a new property. See MPEP § 2112. The burden remains on the applicant to show the unobvious difference between the instantly claimed invention and the prior art that would render patentability unto the instantly claimed invention.

The present amendment to the claims does not overcome the prior art rejection of record. The applicant has attempted to distinguish the instant claims over the disclosure of the prior art by stating that the a patient having a mass of 70 kg would be administered 7 mL of liquid extract per day. However, a very simple unit conversion would show that 7 mL is equivalent to less than 0.25 fluid ounces. For the sake of comparison, the applicant's recited upper limit of 6 ounces of *Morinda citrifolia* juice per day is equivalent to 177.44 mL per day. By the disclosure of the prior art, such a quantity would be sufficient to treat a patient having a mass of at least 88 kg. Therefore, the applicant's present amendment to the claims, which falls under new matter in the view of the examiner, does not even overcome the disclosure of the prior art.

All claims remain rejected.

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Correspondence

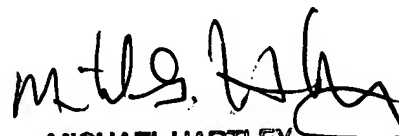
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL HARTLEY
PRIMARY EXAMINER